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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,340	05/15/2001	Thomas J. Hosted JR.	IN01164K	9296
24265	7590	05/06/2005	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,340

Applicant(s)

HOSTED ET AL.

Examiner

Gerald G. Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-18,21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,8-18,21 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Exhibit A

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of an amendment, filed 2/23/2005, in which several claims were amended (claims 1, 6, 8, 18 and 21), claims were cancelled (claims 2-4) and in which new claims were added (claims 24-26). Claims 1, 6, 8-18, 21 & 24-26 are pending in the instant application.

Any rejection of record in the previous office action mailed on 8/23/2004 not addressed herein is withdrawn. In that office action the examiner rejoined embodiments of the invention directed to SEQ ID NO: 6 with the elected claims and invited applicants to submit claims directed to those embodiments. Applicants subsequently submitted a new claim directed to SEQ ID NO: 6 in the response filed on 2/23/2005 (claim 24). New claim 24 is rejected in the instant office action over the art of record. This action is not final, however, due to the fact that the examiner invited applicants to submit claims directed to this subject matter in the first office action on the merits of the case.

Sequence Compliance

Receipt is acknowledged of a supplemental sequence listing, computer readable form (CRF) and attorney's statements that were filed on 1/24/2005. The application is now in sequence compliance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 8-18, 21 & 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Hosted et al (US 2004/0101832 A1; see the entire application) and Hosted et al (U.S. Patent No. 6,861,513 B2; see the entire reference). **This rejection is maintained for reasons of record in the office action mailed 8/23/2004, which grounds for rejection are repeated below. These grounds of rejection are extended to new claims 24-26.**

The applied reference has a common assignee and common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

U.S. Patent No. 6,861,513 and U.S. 2004/0101832 are derived from the same application (U.S. Serial Application No. 09/758,759). All of the citations presented below are taken from the published application.

Hosted et al teach nucleic acids and vectors encoding an *M. carbonacea*-specific integrase gene and the cognate integration sites (e.g. Figures 9A & 9B; paragraphs 0028, 0033, 0151; SEQ ID NO: 176). Thus, Hosted et al teach nucleic acids, vectors and host cells that meet the claim limitations.

Response to Arguments

Applicant's arguments filed 2/23/2005 have been fully considered but they are not persuasive. The response essentially argues: **1)** the examiner does not appear to allege that claimed SEQ ID NO: 2 (i.e. the pMLP1 *xis* gene) is anticipated by Hosted et al, **2)** it is unclear whether the Hosted et al application discloses SEQ ID NO: 2 at all, **3)** SEQ ID NO: 2 does not bear any particular homology to SEQ ID NO: 176 of the Hosted et al reference, **4)** applicants own BlastN comparison of the two sequences shows no significant homology between the two sequences, **5)** Hosted et al does not anticipate any of claims 8-18, 25 and 26 since these claims specifically recite SEQ ID NO: 2, and **6)** rejection of new claims 25-26 is not warranted since the recited method is patentable.

The paragraphs and Figures cited by the examiner in making the rejection do indicate that the Hosted et al reference teaches the cloning and sequences of the *int*, *xis* and *attP* sequences from pMLP1 (e.g. paragraph [151] of the Hosted et al application). Moreover, the plasmid constructs and transformants taught in the Hosted et al application for obtaining the pMLP1 sequences appear to be the same as those taught in the instant specification (i.e. compare the constructs taught in Example 3 of the Hosted et al reference to those taught in the working examples of the instant specification). For example, Example 3 (paragraphs [0151-0154]) of the Hosted et al application teach the construction of the integration vector pSPRH840 that comprised the pMLP1 *int*, *xis* and *attP* sequences and which was used to determine the corresponding nucleotide sequence for each (e.g. see Figure 7a of the Hosted et al reference). This same vector is taught in the instant specification (e.g. Example II and Figure 2). In addition, the strain used in the Hosted et al reference to identify the right attP/attB junction

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sequence for *M. carbanaceae* transformed with pSPRH840 (i.e. *M. carbanaceae* SCC1413) is the same as taught in the instant application (i.e. *M. carbanaceae* var. *africana* ATCC39149 as cited in Example II), as evidenced by the ATCC catalog (see attached Exhibit A). With regard to claims 25 and 26, Hosted et al teach the transformation of *M. carbanaceae* SCC1413 and *M. halophitica* SCC760 with pSPRH840, which necessarily comprises the pMLP1 *xis* gene. The reference further teaches the isolation and sequencing of the *M. carbanaceae* SCC1413 chromosomal region comprising the phage/bacterial chromosome junction, which would be expected to correspond to SEQ ID NO: 6 of the instant application (e.g. paragraph [153]).

Given that the Hosted et al reference teaches the construction, sequencing and use of the same constructs comprising the pMLP1 *int*, *xis* and *attP* sequences, the skilled artisan would necessarily expect that Hosted et al teach isolated polynucleotides comprising SEQ ID NO: 2 and SEQ ID NO: 6. Applicants are invited to provide an explanation for why the constructs taught by Hosted et al would not comprise the recited sequences of the instant claims, particularly since the Hosted et al reference has inventors in common with the instant application.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

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Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G. Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl


GERRY LEFFERS
PRIMARY EXAMINER